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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,856	07/18/2006	Phillip Vollmers	043043-0359294	3217

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
10/17/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Claims 27-32, 34, 36-43 and 48-59 are all the pending claims.

2. Claim 35 was cancelled and Claims 27-29, 31-32, 36-39, 42-43, 49, 51-59 were amended in the Response of 9/28/11.

3. Claims 27-32, 34, 36-43 and 48-59 are all the pending claims for this application.

4. This Office Action is final.

Information Disclosure Statement

5. The IDS of 9/27/11 has been considered and entered. The initialed and signed 1449 form is attached.

Withdrawal of Objections

Claim Objections

6. The objection to Claim 37 because of informalities is withdrawn.

Claim 37 recites "said heavy chain (VL) variable region" and has been amended to recite "said heavy chain (VH) variable region."

Withdrawal of Rejections

Claim Rejections - 35 USC § 112

Written Description

7. The rejection of Claims 27-32, 34-43 and 48-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

The specific antigen in the LDL and oxLDL, at least based on the commercial ELISA kit description in the specification on p. 14, is actually for apolipoprotein B and to which the antibody (SAM-6 and/or SAM-6.10) is disclosed and claimed as binding.

Claim Rejections - 35 USC § 102

8. The rejection of Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Giles-Komar et al. (WO200212502; filed 8/7/01) is withdrawn.

Claim 43 has been amended to recite the CDRs 1-3 for the VH domain (SEQ ID NO:3).

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. The provisional rejection of Claims 27-32, 34, 36-43 and 48-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 73, 80, 81, 106-112, 115, 116 and 122-124 of copending Application No. 10/579,290 (US 20080108133) is maintained.

The rejection was set forth in the Office Action of 12/10/10 as follows:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite the same sequenced for the VH and VL domains of the claimed antibodies.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejection was set forth in the Office Action of 12/10/10 as follows:

"Applicants request on p. 15 of the Response of 4/11/11 (and 4/15/11) to hold the rejection in abeyance until all rejections are withdrawn is granted. The rejection is maintained."

Applicants allege on p. 11 of the Response of 9/28/11 it is appropriate to withdraw the rejection because co-pending application no. 10/579,290 has not been allowed, and furthermore, is not in allowable condition nor is in an advanced stage of prosecution, as compared to the subject application.

Response to Arguments

Initially, the examiner submits that MPEP 804 (B) does not apply to the instant case where both applications share the same filing dates: "If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP

rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer."

Further, it is noted that Applicants do not dispute that the claims between the conflicting cases are not patentably distinct. The instant examiner proffers that patent term is only one of two reasons why the Office requires filing a TD.

i) Patent term

If more than one patent could be obtained on the same invention, an inventor could extend the period of exclusivity beyond what the law intends (See *In re Goodman*, 11 F3d. 1046, 1053 (Fed. Cir. 1993); *General Foods Corp v. Studiengesellschaft Kohle MbH*, 972 F.2d 1271, 1279-80 (Fed. Cir. 1992) ("The basic concept of double patenting is that the same invention cannot be patented more than once, which, if happened, would result in a second patent which would expire some time after the original patent and extend the protection timewise"). For example, and as in the present case, an inventor could apply for one patent in 2005 and a second on the same invention in 2015, thereby obtaining the equivalent of a 30 year patent. To prevent this result, the previous examiner (and the instant examiner agrees) that where the subject matter is essentially duplicative to that of the '185 patent, the instant claims are unpatentable in the absence of a terminal disclaimer.

ii) One patent to each invention per inventor

TDs are also required to link two cases together so that two patents to the same or a similar invention cannot be sold separately. An inventor is entitled to one patent on one invention (see *In re Leonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997).

The provisional obviousness double patenting rejection may be obviated by filing a terminal disclaimer in accordance with 37 CFR 1.321(d). See MPEP § 804 and § 804.02.

The rejection is maintained.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNN BRISTOL whose telephone number is (571)272-6883. The examiner can normally be reached on 8:00-4:30, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn Bristol/
Art Unit 1643
Primary Examiner